IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TINA L. JONES, and J.J. (Her Son, a minor, twelve (12) years of age),	)	
Plaintiffs,	)	Civil Action No. 05-611 (GMS)
v.	)	
JANSEEN PHARMACEUTICA, and MYLAN LABORATORIES,	)	
Defendants.	)	

BRIEF IN SUPPORT OF THE MOTION TO DISMISS OF MYLAN LABORATORIES INC.

Defendant, Mylan Laboratories Inc. ("Mylan"), respectfully submits the following Brief in Support of its Motion to Dismiss Plaintiffs' Complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Mylan submits that the plaintiffs' Complaint fails to state any legally cognizable claim. Because the Complaint fails to state a claim against Mylan upon which relief can be granted, an Order should be entered by the Court dismissing plaintiffs' claim against Mylan, with prejudice.

I. INTRODUCTION

In this civil action, plaintiffs contend that Tina Jones used the Duragesic® patch, a brand name transdermal Fentanyl patch developed by defendant, Janssen Pharmaceutica ("Janssen"), and thereafter experienced "long-term irreversible effects." *See*, plaintiffs' Complaint, Section (1) of the "Parties to this Action" portion of the Complaint.

Although plaintiffs allege that Mylan manufactured a generic version of the transdermal Fentanyl patch, there is no specific allegation in the Complaint that Ms. Jones ever used a generic version of the Duragesic® patch, or that the injuries or damages which plaintiffs claim to have sustained were caused by the use of Mylan's generic product.

In effect, plaintiffs have commenced litigation against two (2) companies—Janssen Pharmaceutica and Mylan, the alleged manufacturers and suppliers of the Duragesic® patch and its generic equivalent. However, it is nowhere alleged in the Complaint that plaintiffs used the Janssen product, the Mylan product or both. Absent an allegation that Ms. Jones used a Mylan product, the product identification is lacking, and the Complaint fails.

Looking past the product identification issue, the Complaint is fundamentally flawed because plaintiffs never state a cognizable claim against Mylan. Accepting the allegations of the Complaint as true, Ms. Jones alleges nothing more than the fact that she was prescribed the Duragesic® patch and experienced side effects. *See,* plaintiffs' Complaint, ¶¶ 5-8. No attempt is made to plead any legally cognizable claim or cause of action, whether it be based on negligence or some other theory.

Finally, the Complaint purportedly asserts a claim for punitive damages, yet there are absolutely no facts alleged in the Complaint that would establish any intentional, reprehensible or reckless conduct so as to justify such an award. Finally, the plaintiffs have asserted a claim for loss of parental consortium on behalf of Ms. Jones' minor son. The Delaware Courts have never recognized such a claim or cause of action. Consequently, all claims for relief asserted on behalf of the minor must be dismissed.

To summarize, Mylan submits that the Complaint is legally deficient in the following respects:

1) The plaintiffs have not alleged that the injuries Ms. Jones claims were the result of the use or exposure to Mylan's product, and no legally cognizable claim can be asserted against a product manufacturer in the absence of product identification.

2) The Complaint fails to state a claim upon which relief can be granted since no cause of action has been pled.

3) No right or entitlement to punitive damages exists based on the allegations of this Complaint.

4) The claim for loss of parental consortium fails as a matter of law.

II. LEGAL STANDARD

The legal standard for granting a Motion to Dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure is well-settled. A Rule 12(b)(6) Motion to Dismiss requires the Court to determine whether the plaintiff may recover under any reasonably conceivable set of circumstances susceptible to proof under the Complaint. When considering a Motion to Dismiss, the Court must "accept as true the facts alleged in the Complaint and all reasonable inferences that can be drawn from them." Markowitz v. Northeast Landco, 906 F.2d 100, 103 (3d Cir. 1990); Graves v. Lowery, 117 F.3d 723, 726 (3d Cir. 1997). In particular, the Court looks to "whether sufficient facts are pled to determine that the complaint is not frivolous and to provide defendants with adequate notice to frame an answer." Colburn v. Upper Darby Twp., 838 F.2d 663, 666 (3d Cir. 1988). However, the Court need not "credit a complaint's 'bald assertions' or 'legal conclusions' when deciding a motion to dismiss." Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 1997). A Court should dismiss a Complaint "only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." *See,* Graves, 117 F.3d at 726. Thus, in order to prevail on a Motion to Dismiss, a moving party must show "beyond doubt that the plaintiff can prove no set of facts in support of his claim [that] would entitle him to relief." Conley v. Gibson, 355 U.S. 41, 45-46 (1957).

In this Brief, Mylan will demonstrate that no relief can be granted to plaintiffs under any set of facts that could be proved consistent with the allegations contained within the Complaint. For this reason, Mylan requests the entry of an Order dismissing the plaintiffs' Complaint with prejudice.

III. STATEMENT OF MATERIAL FACTS

On August 18, 2005, plaintiffs, Tina L. Jones and her minor son, filed this civil action against Janssen and Mylan.[1] (A copy of the Complaint is attached hereto as Exhibit "A"). Under the section of the Complaint entitled "The Complaint," plaintiffs allege that in September 2004, Tina Jones visited Dr. Jeffery Meyers, a Delaware pain management physician who prescribed the Duragesic® patch to control Tina Jones' long-term pain. (*See* Complaint, at ¶ 3). Plaintiffs further allege that, in addition to the Duragesic® patch, Tina Jones continued to take three other prescribed medications: Soma, Percocet and Lexapro. (*See* Complaint, ¶¶ 2-4). Finally, plaintiffs allege that from the time Tina Jones began taking the Duragesic® patch, she has experienced various side effects which have adversely affected her lifestyle, employment, relationships and ability to perform certain functions. (*See* Complaint, ¶¶ 5-12).

Plaintiffs further contend that "users" of the Duragesic® patch "were not advised that the patch is one-hundred times more potent than heroin, causes addiction, and a multitude of other physical and mental side effects, which removes the quality of life from the user(s)." (*See* Complaint, "Parties to this Action," ¶ (3)).

In their Complaint, plaintiffs contend that Tina Jones "has suffered and continues to suffer irreversible harm by the use of Duragesic® ***Patches***, which were developed and dispensed by the named respondents . . . ." (Complaint, section entitled "Parties to this Action," ¶ 1). In this regard, plaintiffs contend that Janssen developed the Duragesic® patch and holds a trademark on the Duragesic® patch. (*See* Complaint, "Parties to this Action," ¶ (3)). Elsewhere in the Complaint, plaintiffs acknowledge that Duragesic® is a brand name product and distinguish that product from the generic version of the product, which plaintiffs contend was manufactured by Mylan. (*See* Complaint, the Fentanyl Duragesic Patch). In this regard, plaintiffs allege that

[1] At times Janssen is incorrectly identified in the Complaint as "Janseen Pharmaceutica."

Mylan "dispenses" the Duragesic® patch "as a generic potent narcotic medication." (*See* Complaint, "Parties to this Action," ¶ (4)).

However, plaintiffs do not allege that Tina Jones ever used a generic version of the Duragesic® patch or that any of the plaintiffs' claimed injuries and/or damages were caused by Tina Jones' use of a generic version of the Duragesic® patch. Nor do plaintiffs allege that Mylan dispensed any generic version of the Duragesic® patch to plaintiff, Tina Jones.

Finally, in the Complaint, Tina Jones' minor son has asserted a claim for loss of parental consortium. (Complaint, ¶ 12). The minor plaintiff alleges that he has "effectively lost a Mother, he must now fend for himself in many other functions his mother provided prior to the introduction of the Duragesic Patch into her body; he must (1) clean the family home; (3) (sic) Prepare meals; (3) wash and dry his clothing as well as his Mothers (sic); (4) is devoid of a parent at organized sporting events both at school and the community; (4) (sic) has lost the warmth and affection of a once caring Mother who, due to the effects of the Duragesic Patch is unable to emit her care and feelings."

IV. ARGUMENT

A. MYLAN IS ENTITLED TO THE DISMISSAL OF THIS ACTION SINCE THE COMPLAINT NEVER ALLEGES THAT MS. JONES' INJURIES WERE THE RESULT OF HER USE OF THE MYLAN PRODUCT.

On its face, the Complaint is legally insufficient and inconsistent. In effect, plaintiffs have sued two (2) manufacturers under the premise that Ms. Jones was injured through the use of a prescription drug manufactured by one (1) of them. Janssen is the innovator who has marketed and sold the Duragesic® patch. Mylan manufactures a generic equivalent of the Duragesic® patch. As to Mylan, the Complaint fails because plaintiffs have not alleged:

(a) that she was prescribed the generic Fentanyl patch as opposed to the brand product;

(b) that she used the generic product as opposed to the branded product;

(c) that her injuries were the result of the use of the generic product as opposed to the branded product.

The law is clear that product identification is a fundamental and necessary element to any tort claim. Specifically, it has been recognized that a plaintiff must prove a "direct nexus" between a defendant's product and their alleged injuries. *See*, Money v. Manville Corporation Asbestos Disease Compensation Fund, 596 A.2d 1372 (Del. 1991). Simply stated, there must be a "product nexus" or a factual connection between the plaintiff and a particular defendant's product. In this case, the Complaint fails to establish such a nexus. The mere fact that Mylan manufactured a generic Fentanyl patch is not enough to prove or establish liability. A fair reading of the Complaint suggests that this is the only allegation which the plaintiffs have made. Absent an allegation that Ms. Jones used the generic Fentanyl patch and suffered injuries as a result, the product nexus necessary for liability is lacking, and this Motion to Dismiss must be granted.

B. THE COMPLAINT FAILS AS A MATTER OF LAW SINCE NO LEGALLY COGNIZABLE CAUSE OF ACTION HAS BEEN ASSERTED.

A fair reading of the plaintiffs' Complaint establishes nothing more than the fact that Ms. Jones took a pharmaceutical product manufactured by someone and experienced side effects. However, the law is well-settled that the mere fact of an injury is insufficient to establish liability. Thus, an injury is compensable only if it is predicated upon a legally valid and cognizable cause of action. In Delaware, strict liability is not recognized. *See*, Cline v. Prowler Industries of Maryland, Inc., 418 A.2d 968 (1978). Thus, any cause of action must be presumably predicated upon a negligence theory. To prove negligence, the plaintiffs must establish that the defendants owed a duty and that the defendants, by their conduct, breached that

duty, proximately causing damage. *See*, Elmer v. Tenaco Resins, Inc., 698 F. Supp. 535 (D. Del. 1988).

Reviewing the plaintiffs' Complaint, it is clear that no facts have been established to satisfy any prong of a negligence cause of action. There is nothing on the Complaint to put Mylan on notice as to what conduct is at issue; what claims are being asserted or what the factual basis for those claims may be. Pleading the fact of an injury is wholly insufficient, and it is submitted that the Complaint must be dismissed since it utterly fails to set forth a legally cognizable claim.

C. NO BASIS FOR A PUNITIVE DAMAGE CLAIM EXISTS.

To recover punitive damages, the conduct of the defendant must be intentional, reprehensible or reckless or show a conscious indifference to the plaintiff's life or well-being. Jardel Co. v. Hughes, 523 A.2d 518 (1987). While plaintiffs seek punitive damages under the "Relief Requested" portion of the Complaint, there is no allegation of any intentional, reckless or reprehensible conduct on the part of the defendants to justify such an award.

D. THE CLAIM FOR LOSS OF PARENTAL CONSORTIUM FAILS TO STATE A CAUSE OF ACTION AS A MATTER OF LAW.

In the Complaint, Jones alleges that her minor son has "effectively lost a Mother, he must now feign for himself in many other functions his mother provided prior to the introduction of the Duragesic Patch into her body; he must (1) clean the family home; (3) (sic) Prepare meals; (3) wash and dry his clothing as well as his Mothers (sic); (4) is devoid of a parent at organized sporting events both at school and the community; (4) (sic) has lost the warmth and affection of a once caring Mother who, due to the effects of the Duragesic Patch is unable to emit her care and feelings." *See* Complaint, ¶ 12.

Essentially, these allegations attempt to state a claim for loss of parental consortium. However, as noted by this Court, Delaware courts have yet to hold that recovery is possible for loss of consortium, except as between a husband and wife. Smith v. Town of Dewey Beach, 659 F. Supp. 752 (D. Del 1987). As such, the minor plaintiff's claim for loss of his mother's consortium is not a claim upon which relief may be granted.

V. CONCLUSION

For the reasons stated herein, Mylan Laboratories Inc. respectfully requests the entry of an Order granting its Motion to Dismiss.

Respectfully submitted,

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